IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gholam-Reza Zadno-Azizi, *et al.*
Serial No.:	10/081,569
Conf. No.:	4156
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For:	*BODY FLUID FLOW CONTROL DEVICE*
Art Unit:	3738
Examiner:	Urmi Chattopadhyay

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ANTONY FIELDS UNDER 37 C.F.R. §1.132

I, Antony Fields, do hereby declare as follows:

1. I am Vice President of Research and Development for Emphasys Medical, Inc., assignee of the above-captioned patent application, U.S. Patent Application Serial No. 10/081,569 ("the '569 application"). I received my MSc degree in Control Systems from Imperial College of Science and Technology, University of London, in London, England in 1988. I received my M.S. degree in Mechanical Engineering from the Massachusetts Institute of Technology, in Cambridge, Massachusetts in 1985 and my B.S. degree in Mechanical Engineering from University of California, Berkeley in 1983. Since July 2000, I have managed all research and development for Emphasys Medical relating to flow control devices implantable in the lung for the treatment of emphysema and chronic obstructive pulmonary disease. A copy of my *curriculum vitae* is attached hereto as Exhibit 1.

The '569 Application

2. I have reviewed the '569 application, including claims 16-19.

3. I am aware of the U.S. Patent Office rejection of claims 16-19 of the '569 application under 35 U.S.C. §112 under enablement and written description grounds.

4. I am informed that the enablement requirement means that a specification must provide teachings that permit a person of skill in the art to make and use the invention without having to undertake undue experimentation. I am informed that undue experimentation would be manifest when efforts are required that are considered outside of or beyond the efforts normally expected in the field. Accordingly, routine design choices would not be considered undue experimentation, but the need to undertake comprehensive changes or extensive supplemental efforts to a disclosure would amount to undue experimentation. I have reviewed the '569 application with these principles in mind.

5. I also am informed that an application must contain a written description of the claimed invention. I am informed that the written description requirement means that a specification must contain sufficient disclosure to show that the inventors possessed the claimed invention. I have reviewed the '569 application with these principles in mind.

6. The '569 application describes a fluid flow control device for pulmonic placement in the human body. See page 3, lines 4-6 of the '569 application. According to the '569 application, the fluid flow control device for pulmonic placement includes a resilient seal capable of sealing within the interior of a body passageway. The resilient seal can be a cylindrical

elastomeric or polymeric material. See page 4, lines 3-6 of the '569 application. The resilient seal has a substantially circular cross-section to fit within the body passageway, and an outside diameter of approximately 0.349 inches [8.865 mm], for example. See page 4, lines 8-9 and page 7, lines 5-6 of the '569 application. The outside diameter of the resilient seal coincides with the outside diameter of the fluid flow control device. See Figure 2 of the '569 application. The fluid flow control device described in the '569 application has a length of approximately 0.60 inches [15.24 mm]. See page 7, lines 6-7 of the '569 application.

7. According to the '569 application, the fluid flow control device further includes a frame that is located within the resilient seal. See page 5, lines 10-11 of the '569 application. The frame is capable of expanding from an insertion state to an anchor state. In the anchor state, the frame has a diameter that is larger than in the insertion state. See page 6, lines 1-6 and page 9, line 21-page 10, line 1 of the '569 application. In the expanded state, the flow control device fits with interference in the body passageway. See page 6, lines 6-7 of the '569 application.

8. According to the '569 application, the fluid flow control device also includes a valve body that provides one-way flow restriction. See page 2, lines 13-16 of the '569 application. The valve acts as a one-way valve that opens when a threshold pressure is applied to one end of the valve. See page 4, line 22-page 5, line 4 of the '569 application.

Placement of the Fluid Flow Control Device in the Lung

9. As discussed above, the '569 application describes a fluid flow control device for pulmonic placement in the human body. It is my expert

opinion that, based upon the meaning of "pulmonic", the '569 application describes a fluid flow control device for placement in the lung. Merriam Webster's Collegiate Dictionary defines "pulmonic" as "pulmonary", which is defined as "relating to, functioning like, or associated with the lungs." See Merriam-Webster's Collegiate Dictionary, Tenth Edition (1993), page 946, attached hereto as Exhibit 6.

10. As discussed above, the '569 application states that the fluid-flow control device fits with interference in the body passageway. I interpret this to mean that the fluid-flow control device can be an obstructing member. My interpretation is based on the dictionary definition of "interference." Merriam Webster's Collegiate Dictionary defines the word "interference" as "obstruction." See Merriam-Webster's Collegiate Dictionary, Tenth Edition (1993), page 610, attached hereto as Exhibit 6.

11. It is my expert opinion that air flows through bronchial passageways of the lung and that air is a fluid. Merriam Webster's Collegiate Dictionary defines "fluid" as "a substance (as a liquid or gas) tending to flow or conform to the outline of its container." See Merriam-Webster's Collegiate Dictionary, Tenth Edition (1993), page 449, attached hereto as Exhibit 6.

12. As discussed above, the fluid flow control device described in the '569 application has an outer diameter of approximately 0.349 inches [8.865 mm] and a length of approximately 0.60 inches [15.24 mm]. Published empirical data indicates that a sub-branch of a human bronchial passageway can have an average diameter of up to about 9.10 ± 2.05 mm and a length of up to about 19.83 ± 7.78 mm. See Nikiforov *et al.*, MORPHOMETRIC VARIABILITY OF THE HUMAN UPPER BRONCHIAL TREE (1982), Table 1, page 292, attached

hereto as Exhibit 2. Accordingly, the fluid flow control device described in the '569 application has a diameter and length that is dimensioned for insertion into a sub-branch of a human bronchial passageway.

13. The fluid flow control device described in the '569 application is placed in a bronchial sub-branch that provides fluid flow to and from a portion of a human lung (the "lung portion"). When the fluid flow control device is placed in such a bronchial sub-branch, the expandable frame exerts a radially-outward pressure against the resilient seal and presses the resilient seal against the inner wall of the bronchial sub-branch. Because the resilient seal and the bronchial sub-branch both have a substantially circular cross-section, the radial pressure on the resilient seal causes the seal to make continuous contact with the inner wall and seal with the inner wall. The fluid flow control device then obstructs the bronchial sub-branch such that air would be required to flow through the one-way valve in order to flow into and out of the lung portion through the bronchial sub-branch. The fluid flow control device can be oriented in the bronchial sub-branch such that one-way valve permits fluid flow in an exhalation direction and prohibit fluid flow in an inhalation direction through the bronchial sub-branch. Consequently, the fluid flow control device precludes fluid, such as inhaled air, to flow into the lung portion and permit fluid, such as air, to flow from the lung portion through the bronchial sub-branch.

14. Placement of the flow control device in the bronchial sub-branch as described above precludes normal function of the lung portion. The one-way valve of the flow control device prohibits inhaled air to flow into the lung portion through the sub-branch, and permits air within the lung portion to flow out of the lung portion through the sub-branch. When the flow control device is left in the

bronchial sub-branch for a sufficient amount of time under such conditions, the lung portion collapses, which results in a reduction of the size of the lung.

15. Attached hereto as Exhibit 3 is a CD-ROM containing two digital video files entitled "Endobronchial Valve for Emphysema" (the "Endobronchial Valve Video") and "Valve Placement Example" (the "Valve Placement Video"). The Endobronchial Valve Video and Valve Placement Video include video footage describing and showing the placement of flow control devices comprised of endobronchial valves into bronchial passageways of a patient's lung. See Endobronchial Valve Video, 1:20-3:35 and Valve Placement Video. Each of the endobronchial valves used in the Endobronchial Valve Video includes a resilient seal capable of sealing within the interior of a body passageway, a frame located within the resilient seal, and a one-way valve. The flow control devices were placed in the lung such that the one-way valves permit exhaled air to flow from the right upper lung lobe and preclude inhaled air from flowing into the right upper lung lobe. The Endobronchial Valve Video and Valve Placement Video show that the flow control device, when placed in the patient's bronchial passageway, makes continuous contact and seals with the inner dimension of the bronchial passageway. See Endobronchial Valve Video, 3:28-3:34 and Valve Placement Video. As shown in the Endobronchial Valve Video, the placement of the flow control devices in the patient's lung resulted in collapse of the right upper lung lobe. See Endobronchial Valve Video, 3:35-3:46. The Endobronchial Valve Video demonstrates that a flow control device having a resilient seal capable of sealing within the interior of a body passageway, a frame located within the resilient seal, and a one-way valve (as described in the '569 application) can be placed in a bronchial sub-branch of a

lung to result in collapse of a portion of the lung and reduction of the size of the lung.

16. As Exhibit 4, I provide an Emphasys 8.0 Bronchial Valve™, Catalog No. EBV-8.0 ("the EBV 8"), which is like the valves inserted in the above-discussed videos. This class of valve is schematically depicted in Figures 1 and 2 of the captioned application. The EBV 8 has a valve body (24) and a slit (26) and metal cylinder (32) having extending elements (34). The EBV 8 has additional enlarged disk elements coaxially disposed on cylindrical element (36) so as to surround the valve.

17. Claim 20 of the captioned application relates to a "pulmonic fluid flow control device." The EBV 8 is a pulmonic fluid flow control device in that it is a valve for placement in the lung. Claim 20 recites that the device comprises "a one-way valve dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow." The EBV 8 is dimensioned for placement in a bronchial passageway and is, therefore, "dimensioned for pulmonary placement." The EBV 8 is "configured to restrict fluid flow" in that the valve is a one-way valve that restricts fluid therethrough.

18. As Exhibit 5, I provide a document entitled "Emphasys Endobronchial Valve System Instructions for Use" ("the Valve Instructions"), which provide instructions for placing devices such as the EBV 8 in a bronchial passageway. Page 1 of the Valve Instructions includes a photograph labeled to show that the device includes a seal and a valve. Page 1 of the Valve Instructions states that the device is implanted in a target bronchus. Page 3, paragraph 5 of the Valve Instructions indicates that the device should be

deployed in the bronchus such that the "entire circumference of the large seals should contact the bronchial wall."

19. As stated above, I am informed that the enablement requirement means that a specification must provide teachings that permit a person of skill in the art to make and use the invention without having to undertake undue experimentation. It is my expert opinion that the '569 application enables the claimed invention in that the specification describes the structural components, shapes, dimensions, and materials that would enable one of skill in the art to make the pulmonic fluid-flow control device and system of claims 20-25 and the bronchial sub-branch obstruction device and system of claims 16-19. For example, the specification states that the fluid-flow control device has a frame, a seal, and a valve, which are the basic components of a pulmonic fluid-flow control device. The specification describes exemplary materials for manufacturing the frame, seal and valve. For example, the specification states that the frame can be manufactured of a metal, such as a nickel titanium alloy (a biocompatible material) and that the seal and valve can be manufactured of a polymeric material.

20. The specification also states that the device is generally cylindrical and of substantially circular cross-section, and that the device has an exemplary outer diameter and length of approximately 0.349 inches and approximately 0.60 inches, respectively. Such a fluid-flow device is dimensioned for pulmonary placement in that it fits within a bronchial passageway. The specification also describes various embodiments of valves that successfully restrict fluid flow through a pulmonic passageway, such as the valve body with a slit that opens when a threshold pressure is encountered. In

addition, the specification describes an outer sheath and an elongate passage that can be used to position the fluid flow control device. In view of the extensive description provided by the specification, it is my expert opinion that the '569 application enables a person of skill in the art to make the pulmonic fluid flow control device and system of claims 20-25 without undertaking undue experimentation.

21. It is further my expert opinion that the '569 application enables a person of skill in the art to make the bronchial sub-branch obstruction device and system of claims 16-19. These claims essentially relate to a device having a one-way valve that fits within a bronchial passageway wherein the device blocks fluid flow in one direction through the passageway and permits fluid flow in an opposite direction through the passageway. The specification describes a device having a diameter and length that fits within a human bronchial sub-branch, and having a cross-sectional shape that makes continuous contact with an inner dimension of the bronchial sub-branch. The specification also describes a one-way valve that permits fluid to flow in one direction and precludes fluid from flowing in an opposite direction.

22. It is my expert opinion that the fluid-flow control device described in the '569 application inherently performs the functions of sealing a bronchial sub-branch upon placement in the bronchial sub-branch, precluding normal function of a lung portion, and collapsing the portion of the lung for reducing the size of the lung, as contained in claims 16-19. My opinion is based on the '569 application describing a fluid-flow control device having dimensions that necessarily fit into a human bronchial sub-branch and components that necessarily result in the aforementioned functions when

placed in a bronchial sub-branch. Because the '569 application discloses a device that inherently performs the aforementioned functions, the application necessarily discloses the functions. The foregoing is evidenced by the Endobronchial Valve Video and Valve Placement Video, which show an obstruction device that conforms to the specification of the '569 application and that is placed in a bronchial sub-branch, resulting in sealing of the bronchial sub-branch, preclusion of the normal function of the lung, and collapse of the lung portion for reducing the size of the lung.

23. As stated above, I also am informed that an application must contain a written description of the claimed invention and that the written description requirement means that a specification must contain sufficient disclosure to show that the inventors possessed the claimed invention. I am aware that the written description mandates more than mere repetition of the claim language in the specification. I believe that the '569 application provides a written description of the pulmonic fluid flow control device and system of claims 20-25 and the bronchial sub-branch obstruction device and system of claims 16-19. The specification states that the fluid flow control device is for pulmonic placement. I interpret this to mean that the fluid flow control device can be placed in the lung. The written description supports this interpretation in that the written description describes exemplary dimensions sized to fit in the lung and also describes and shows in Figures 1 and 2 a device that is shaped to fit in the lung.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to

be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

10/15/03
Date

Antony Fields